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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,704	06/01/2001	Randy L. Morningstar	687-442	2503

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Barbara A. Wrigley
OPPENHEIMER WOLFF & DONNELLY, LLP
45 South Seventh Street
Suite 3300
Minneapolis, MN 55402

EXAMINER

ODLAND, KATHRYN P

ART UNIT	PAPER NUMBER
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3743

DATE MAILED: 11/18/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/872,704

Applicant(s)

MORNINGSTAR, RANDY L.

Examiner

Kathryn Odland

Art Unit

3743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-88 is/are pending in the application.
- 4a) Of the above claim(s) 20-51 and 62-88 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19 and 52-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11, 15.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Response to Amendment

This is a response to the amendment dated October 9, 2003. Claims 1-19 and 52-61 are pending.

Response to Arguments

1. Applicant's arguments filed October 9, 2003 have been fully considered but they are not persuasive. Applicant has chosen not to recite structural limitations in the body of the claims, which would define over the prior art of record as well as define the invention in the disclosed medical environment. For example in claim 1, the preamble is simply, "an implantable balloon." The term implantable is extraordinarily broad and given a reasonably broad interpretation this limitation is met by anything that is capable of being implanted. Further, there is a lack of structural features in the body of the claim to further define the structure over Hoffman. Moreover, there is no amplification in the body of the claim to require a medical environment and given the balloon of Hoffman is capable of being implanted, the rejection is reiterated. Moreover, there is clear motivation to combine the teachings of Copenhaver et al. with Hoffman for the purpose of preventing backflow and enhancing seal properties. Obtaining a proper seal is key for balloon type devices.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-9, 11-13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman in US Patent No. 4,327,912.

Regarding claims 1-9, Hoffman discloses a balloon (12') having a valve portion (generally 66) having a valve body defining an inlet (74); a valve stem (68) extending from the body opposite the inlet; a piercing (76) extending from the inlet, through the body and the stem, the valve portion constructed from a soft, elastomeric material having memory thereby causing the piercing to remain closed and fluid-tight unless penetrated by a relatively rigid member, as recited in column 5, lines 45-68, column 6, column 7 and seen in figures 16-19; a balloon portion (12'), integral with the valve portion (66), constructed and arranged to receive and hold fluids exiting the piercing (76) opposite the inlet, as recited in column 5, lines 45-55; a valve stem (68) that has at least one side (70, 72) as seen in figure 17; a valve that has a rounded tip, as recited in column 5, lines 52-55 and seen in figures 21 and 22 (where the current application does not distinguish in which dimension the tip is rounded; therefore, edge dimensions of the tip that are rounded fall within the scope); a valve stem (68) that has a side (70, 72) and the valve portion (generally 66) further has a sidewall (inner portion of 12'), laterally displaced from the valve stem side, and integral with an inside surface of the balloon portion, as seen in figure 16 and 17; a valve portion (generally 66) that is *substantially* cylindrical, as recited in column 5, lines 52-55 and seen in figures 17, 21 and 22; a valve body, valve stem (68), and inlet that

are *substantially* cylindrical and *substantially* concentric, as recited in column 5, lines 52-55 and seen in figures 17, 21 and 22; a valve stem (68) that has at least one side (70, 72) and the piercing (76) extends through the side of the stem, seen in figure 17; and a valve body (66) that forms a curved web (see figure 18), integrally connecting the valve portion sidewall (inner portion of 12') with the valve stem (68) side where the curved web is concave and opening toward the balloon portion, as seen in figure 17 and 18.

With regard to claims 11-13 and 16, Hoffman discloses a cylindrical valve body (66) having a predetermined diameter and an upper side and a lower side; an inlet (at 74) defined by the valve body lower side; a cylindrical valve stem (68) extending upwardly from the valve body where the valve stem has a diameter smaller than the valve body diameter, as seen in figure 18; a balloon wall (12') extending upwardly from the valve body where the balloon wall has an inner diameter, while in the deflated state, which is larger than the valve stem such that an annular space exists between the balloon wall and the valve stem and the balloon is deflated, the annular space provided to relieve stress from a union of the balloon wall and the valve body when the balloon is inflated, (where given the structure in a deflated state there would be an annular space between 12' and 68); a piercing (76) extending from the inlet through the valve body and through the valve stem, into an inner chamber defined by the balloon, the piercing constructed and arranged to remain closed unless a substantially rigid member is pushed through the piercing such as to inflate the balloon whereby the piercing

(76) recloses after the member is withdrawn, thereby preventing a fluid from escaping from the inner chamber, as recited in column 5, lines 45-68, column 6, column 7, column 8 and seen in figure 17; an inlet, valve body (generally 66) and valve stem (68) that are substantially concentric, sharing a common longitudinal axis, as seen in figure 17; a piercing (76) that follows the longitudinal axis, as seen in figure 17; and an annular space (defined by inner portion of 12') that is defined on a lower side by a curved web which is concave and opening upwardly, as seen in figure 18.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 10, 14-15, 17-19, 52-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman in US Patent No. 4,327,912 in view of Copenhaver et al. in US Patent No. 5,720,734.

Hoffman discloses the invention as applied to claims 1-9, 11-13 and 16 including a substantially cylindrical body defining an inlet (generally at 74), concentric with the body, opening in a direction opposite the balloon, as seen in figure 16 and 17; a valve stem (68), integral with the body, having a substantially cylindrical side and rounded tip opposite the body leading into an interior of the balloon, as recited in column 5, lines 45-68 and seen in figure 16, 17, 21, and 22;

a piercing (76), defined by the valve body (66) and valve stem (68), extending from the inlet toward the balloon and leading to the interior of the balloon, as seen in figure 17; a cylindrical sidewall (inner surface of 12'), integral with the body extending in a direction toward the balloon, radially displaced from the stem side thereby creating an annular space between the stem and the sidewall, the sidewall having an external surface attachable to the balloon, as discussed in columns 5-8 and seen in figures 16-18; a curved portion (see figure 18) concave so as to open up toward the balloon interior, connecting the sidewall (inner portion of 12') with the stem (68); an end portion, integral with and extending from the sidewall, which curves inwardly to define an opening having an inner diameter which is smaller than an inner diameter of the cylindrical sidewall, as seen in figure 17 and 18; and a valve that is unitarily constructed from an elastomeric material, as recited in column 4, lines 65-68.

However, Hoffman does not explicitly recite a piercing that has a bend that curves toward the stem side; a piercing that has a straight portion and a curved portion where the straight portion extends upwardly from the inlet substantially parallel to the axis and the curved portion extends from the straight portion to a side of the valve stem; a cylindrical wall that has a lower sidewall and an upper sidewall and a taper connecting the lower sidewall and the upper sidewall, whereby the lower sidewall has a larger outside diameter than an outside diameter of the upper sidewall; upper and lower sidewalls that have substantially equal inner diameters; elastomeric material that is silicone; a removable skirt

extending downwardly from the valve body where the skirt provides a surface that may be handled during a balloon manufacturing operation without damaging the balloon wall or the valve body; a removable skirt that has an outside diameter that is smaller than an outside diameter of the valve body such that a ridge is formed between the valve body and the skirt; a skirt that extends from the body in a direction opposite the balloon; or a skirt that is sized to frictionally fit within an open end of a dipping tube.

On the other hand, Copenhaver et al. teach a piercing having a curved portion, as seen in figure 2 and a piercing having a straight portion and a curved portion, where the straight portion extends upwardly from the inlet and substantially parallel to the axis, the curved portion extends from the straight portion to a side of the valve stem, as seen in figure 2. Therefore, it would be obvious to one with ordinary skill in the art to modify the invention of Hoffman to incorporate a piercing having a curved portion; and a piercing having a straight portion and a curved portion, where the straight portion extends upwardly from the inlet and substantially parallel to the axis, the curved portion extends from the straight portion to a side of the valve stem for purpose of enhanced sealing properties where the piercing better closes to prevent backflow.

Moreover, a skirt extending from the body in a direction opposite the balloon; a skirt has an outer diameter smaller than an outer diameter of the valve body, thereby providing a visual and tactile definition of an extent of the skirt, such that the skirt may be removed without removing material from the valve

body; and a skirt that is sized to frictionally fit within an open end of a dipping tube would also be obvious to one with ordinary skill as obvious manufacturing techniques.

Additionally, the specification of the current application fails to demonstrate the criticality of silicone. Therefore, an elastomeric material that accomplishes the function of achieving a fluid tight seal would be obvious to one with ordinary skill in the art.

Also, a cylindrical wall that has a lower sidewall and an upper sidewall and a taper connecting the lower sidewall and the upper sidewall, whereby the lower sidewall has a larger outside diameter than an outside diameter of the upper sidewall and upper and lower sidewalls that have substantially equal inner diameters can be considered a matter of design choice and obvious to one with ordinary skill in the art.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Odland whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KO



Henry A Bennett
Supervisory Patent Examiner
Group 3700